

REMARKS

In response to the final Office Action mailed May 31, 2006, favorable reconsideration is respectfully requested in view of the above amendments and the following remarks. Applicants have amended claim 6 for purposes of clarity. No new matter has been added. The above amendment is not to be construed as acquiescence to the Examiner's stated grounds for rejections and is made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Claim 6 remains rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. According to the Examiner, claim 6 recites that a predetermined cut-off value is to be used to determine the presence of cancer in a patient, but it is allegedly unclear what this pre-determined cut-off value is or how it will be obtained. The Examiner further asserts that the specification discloses various non-limiting manners in which a pre-determined cut-off could be determined (paragraph bridging pages 127-128 of the specification). On this basis, the Examiner concludes that the claim is indefinite because the specification does not disclose, nor does the claim recite, exactly how the predetermined cut-off value will be determined or how the exact numeric value of the predetermined cut-off will be determined. The Examiner further states that it is unclear whether a measured amount above or below this predetermined cut-off is indicative of lymphoma.

Applicants respectfully traverse this rejection. As set forth above, claim 6 has been amended, for purposes of clarity, to recite that when an amount of polypeptide detected is greater than the predetermined cut-off value, this is indicative of the presence of lymphoma in the patient. However, with respect to the Examiner's assertion that a certain and specific means for determining a predetermined cut-off value be incorporated into the claims, Applicants strongly disagree.

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification...If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 requires no more...The degree of precision necessary for adequate claims is a function of the

nature of the subject matter.” (*Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993, cert. denied, 510 U.S. 1100 (1994))).

It does not follow from the fact that there are numerous non-limiting manners in which a skilled artisan could determine a suitable cut-off value for a given detection methodology that the predetermined cut-off value would be unclear and indefinite to the artisan having skill in diagnostic technologies. To the contrary, the fact that there are multiple ways in which this can be accomplished, and these approaches would be easily recognized and understood in the art to which this invention pertains, argues against the need to restrict the claimed invention in this fashion.

Further, the primary purpose of the indefiniteness requirement is “to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their respective rights.” (*Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.* 73 F.3d 1573, 37 USPQ2d 1365 (Fed. Cir. 1996), quoting *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938)).

Accordingly, to incorporate a specific means for determining a predetermined cut-off value into the claim, as requested by the Examiner, would allow a third party the opportunity to determine a cut-off value by an alternative but equivalent known technique other than that specifically incorporated into the claim, and thereby exploit Applicants’ discovery that the claimed polypeptide is an effective diagnostic marker for lymphoma, all the while practicing outside the scope of protection to which the Examiner asserts that Applicants are entitled. In this instance, the disadvantage is placed on Applicants and the advantage on others, which is submitted to be inconsistent with the spirit and scope of the definiteness requirement as stated by the Federal Circuit.

Further, if there was but one effective manner in which a suitable predetermined cut-off value could be determined for the claimed method, then the Examiner’s position would be more easily understood. This is simply not the case in this instance. What is important in the context of the claimed method is the comparison between the measured amount of the polypeptide and a pre-determined control value, not the specific manner used for arriving at the pre-determined control value. The determination of a suitable control cut-off value for

comparison of diagnostic makers is not in any way a concept or practice that is difficult for an artisan of skill in the diagnostic arts to understand or implement. In fact, it would be well recognized that different cut-off values may have different numeric values and/or use different measures, depending on the specific approach employed, while still being suitable comparative cut-off values in the context of the claimed invention for detecting lymphoma. Reconsideration is respectfully requested.

Claim 6 remains rejected under 35 U.S.C. § 112, first paragraph, because the claim allegedly does not provide enablement for determining the presence of every and any type of cancer in a patient. Applicants respectfully traverse this rejection and submit that an artisan of ordinary skill in the art could practice the claimed invention without undue experimentation. However, in the interest of advancing prosecution, claim 6, part (d), has been amended to specify that the cancer being detected is a lymphoma. Reconsideration is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable consideration and a Notice of Allowance are respectfully solicited.

Respectfully submitted,
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